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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,827	10/01/2001	Shigeki Matsubara		5681

7590 06/24/2004

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,827	MATSUBARA ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 10-1-01.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 22-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 22-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 10-1-01 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/360,686.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10-1-01; 4-6-04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

2. The information disclosure statement filed October 1, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The foreign references are missing.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 22 23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22, line 5, recites "analyzing said transferred body fluid samples". The preceeding text of the claim makes reference to transferring a body fluid sample. As such it is unclear if a single or plurality of samples are transferred. The second

paragraph of the claim beginning with the "when" is directed to conditional occurrences not recited as steps in the process. There is no antecedent basis for the body fluid sample being analyzed on a plurality of analysis items using a plurality of pipettes. The preceding paragraph references a single sample and a single pipette.

Claim 23, recites "avoiding levels of carry-over between said samples in advance." There is no antecedent basis in the claim for "said samples".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 22-23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Shinohara JP 63200066 A.

Shinohara discloses an analyzer generating no interference between reagents, by performing control for altering the measuring order of analytical items on the basis of stored interfering reagent data so as to obtain an order generating no interference relation.

When a plurality of reagents are distributed to successively perform analysis with respect to a plurality of analytical items, the interfering reagent data of the reagents in interference relation to each other among a plurality of the reagents is inputted from a keyboard 1 being an input part and stored in a memory part 3. An insertion control part 7 outputs insertion data performing control for altering the measuring order of analytical

items on the basis of the interfering reagent data so as to obtain an order generating no interference relation. A control part 4 successively performs measuring control on the basis of the analytical item selection data stored in a memory part 2 and alters measuring order on the basis of the signal from the insertion control part 7. A comparing monitor part 6 has a buffer memory and judges whether the reagents contained in the analytical items successively carried out on the basis of the analytical selection data of the memory part 2 fall within the purview of the interfering reagent data with the reference to the interfering reagent data of the memory part 3. (see abstract)

7. Claims 22-23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Makiguchi JP 02087069 A.

Makiguchi discloses the method to avoid the effect of contamination between reagents without lowering a speed of treatment and without loss of the reagents, by providing a means to alter a part or the whole of a specified sequence of analysis.

According to an analytical item request inputted from an operation panel 1, a sample set on a sample disk 2 is sucked by a sampling probe 3 and discharged into a reaction vessel 5 on a reaction disk 4. Sampling of the sample is executed repeatedly from the same sample according to the request, sequentially and in accordance with a sampling quantity for each item. Next, reagents 8 to 11 set on a reagent disk 6 is sucked and discharged by a reagent pipetting mechanism 7 and a reaction is started. In the case when there are a pair of samples among those 8 to 11, which are unavoidable from the effect of contamination, in this stage, the contents thereof are stored beforehand in a microcomputer 14. In the cases when the timing of a reagent discharge

comes in the sequence of the pair and when reaction cells overlap each other on the occasion when the request is made in succession in the sequence of the pair among the reagents 8 to 11, an apparatus is controlled automatically, so as to alter the sequence of analysis. (see abstract)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinohara or Makiguchi as applied to claims 22-23 and 26 above, and further in view of Clark et al. US 5,482,861.

The abstract translation of Shinohara or Makiguchi does not reveal that the type of samples analyzed are immunological or DNA.

Clark et al. disclose an automated, continuous and random access analytical system, having apparatus and methodology capable of simultaneously performing multiple assays of liquid samples using different assay methodologies, and providing continuous and random access while performing a plurality of different assays on the same or different samples during the same time period. The analytical system performs both immunological and DNA analysis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that he device of Shinohara or Makiguchi is capable of performing both immunological and DNA analysis thereby increasing the throughput of samples.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ishizawa, Masato et al.; Tajima, Hideji; Stylli, Chari et al.; Matsubara, Shigeki et al. ; Clark, Frederic L. et al.; Saito et al., and Weyrauch, Bruce et al. disclose automated analyzers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg

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